

# INDUSTRY PERSPECTIVE ON MARKET CONSIDERATIONS FOR SMART TECHNOLOGY

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## DISCLOSURES

- OKT – Strategic Planning & Regulatory Consulting
- OKT<sup>2</sup> – ISO 17025 A2LA Accredited – Independent Test Facility



# OVERVIEW

- Industry Concerns & Market Outlook
- Evaluating Smart Orthopedic Technologies
- Identifying & Addressing Risks
- Challenges & Pitfalls



# DEFINITIONS

- **INNOVATION:**
  - *The process of translating an idea or invention into a good or service that creates value for improving quality of life and for which consumers will adopt.*
- **SMART TECHNOLOGY: ‘Self Monitoring Analysis Reporting Technology’**
  - *Technologies capable to adapt automatically & modify behavior to fit environment, able to sense from stimuli, environment and provide data to analyze.*



# SMART INNOVATION – DETERMINING VALUE

1. Does it offer a solution to a problem that currently does not exist?
2. Is it superior to other conventional products that do not provide solutions, nor address root cause?
3. Is it truly “NOVEL” or just an incremental change?
4. Is it a technology looking for an application?





# SMART ORTHOPEDIC SYSTEMS

## 1. Smart Tools

- RFID tags on surgical instruments
- Smart scalpels, Microneedles – drug delivery

## 2. Smart Implants

- Intraop– VeraSense – TKA alignment
- Long-term implantation

## 3. Smart Diagnostics

- Wearables – monitor
- Lab on a chip

## 4. Smart Treatments

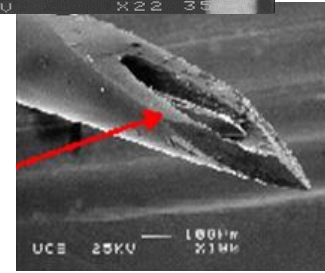
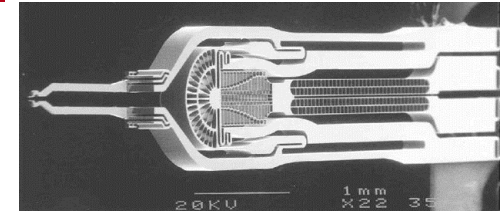
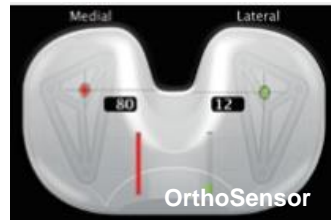
- Drug delivery systems

## 5. Smart Biomaterials

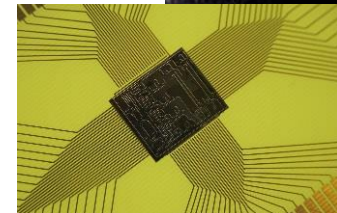
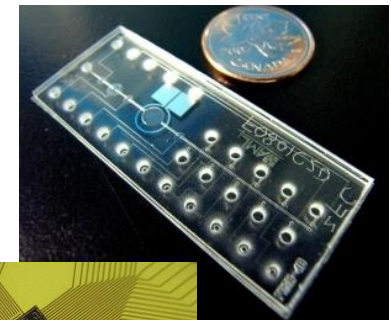
- Polymers – respond differently to different strain rates

## 6. Smart Designs

- Structures that can be control pressures, flow, stress
- Nanosieves



## SMART SYSTEM



# MARKET OUTLOOK

- Sedentary lifestyles, poor nutrition = prevalence of chronic diseases will continue to increase = overburdened healthcare system
- Innovative leaps in medical technology will be crucial
- Current market developments will lead to patient specific treatments using smart devices & machines.
- Logical for long-term economics --- BUT Acceptance & adoption of new technologies necessary



# INDUSTRY CONCERNS

- Must be a disruptive & superior technology for max VALUE
- Must offer superior solution to patient quality of life to increase adoption
- Must be SAFE & EFFECTIVE- and work well!
- Challenging & Costly Regulatory processes
- Reimbursement Challenges post-approvals
- Pricing concerns to recoup development costs & still remain 'competitive'
- Hospital adoption
- Costs & Time to market
- Greater user acceptance & adoption = Greater profit to Industry

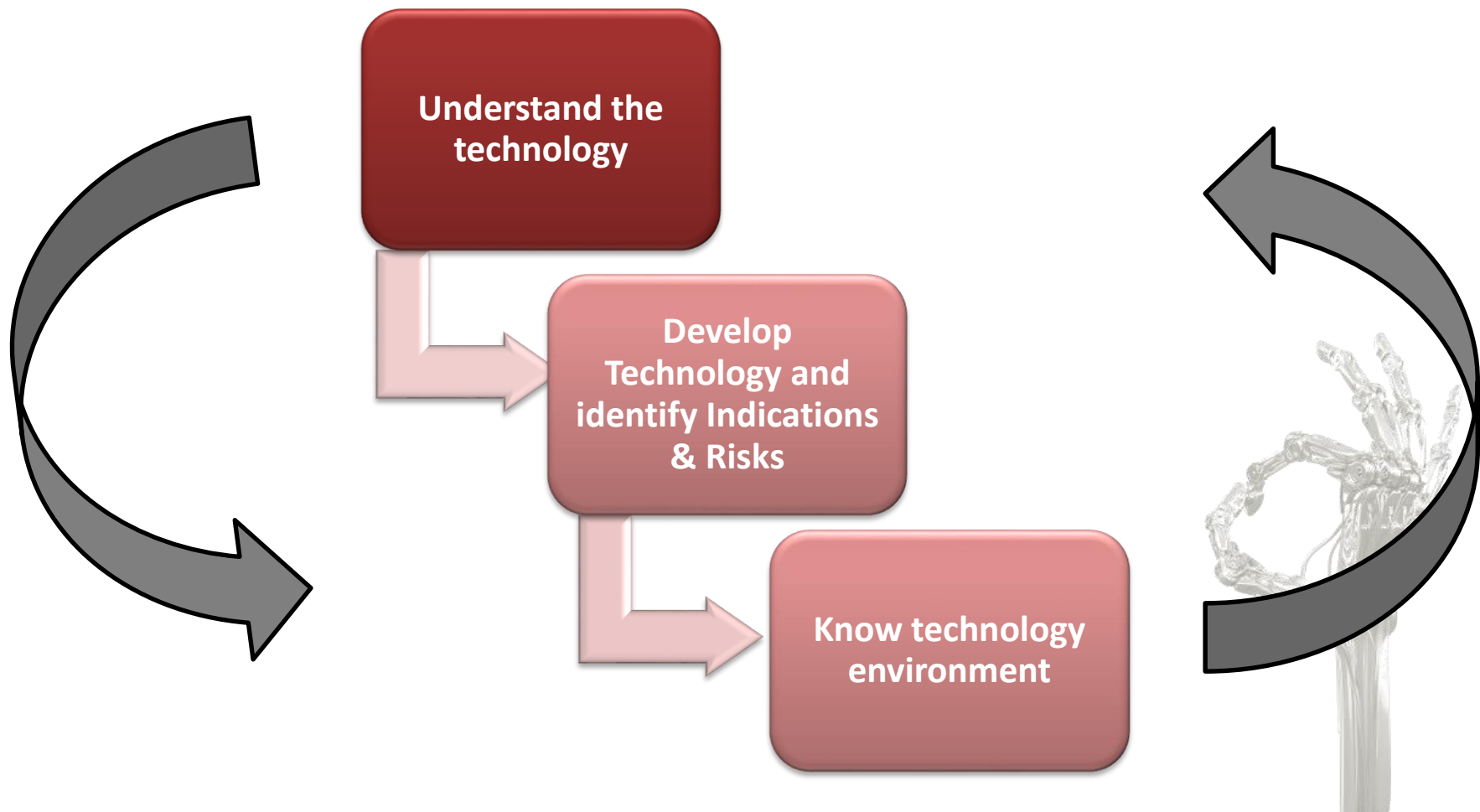




# How do we evaluate Smart Orthopedic Systems?



# SEQUENTIAL PROCESS



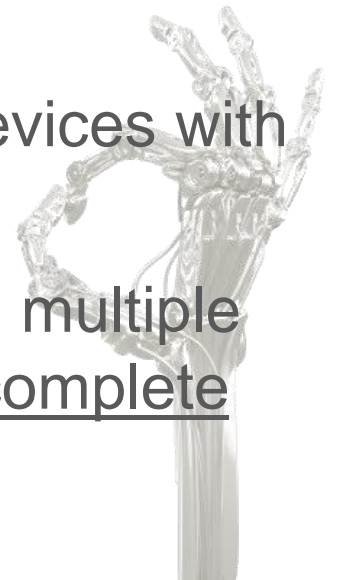
# TESTING & EVALUATING SMART SYSTEMS

1. “System” – Implant +Tooling +Diagnostic + Therapeutic
2. Lack of current test standards & guidelines for these systems
3. Lack of equipment & resources to evaluate new technologies & failures
  - MEMS & Nanosensors/ Nanoparticulate /Micro & Nanoscaffolds
4. Smart implants w/same indications - may differ significantly in what makes them operate in a ‘smart’ manner
5. Although implant may be a 510k item, the addition of smart technologies to the implant & tooling increase the risk, challenges, tests, failure mechanisms, validation processes, and regulatory pathway
6. New Technologies = New Challenges = New Failures & Risks = New Regulations
7. **“Think out of the Box”**

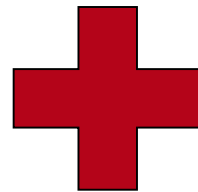
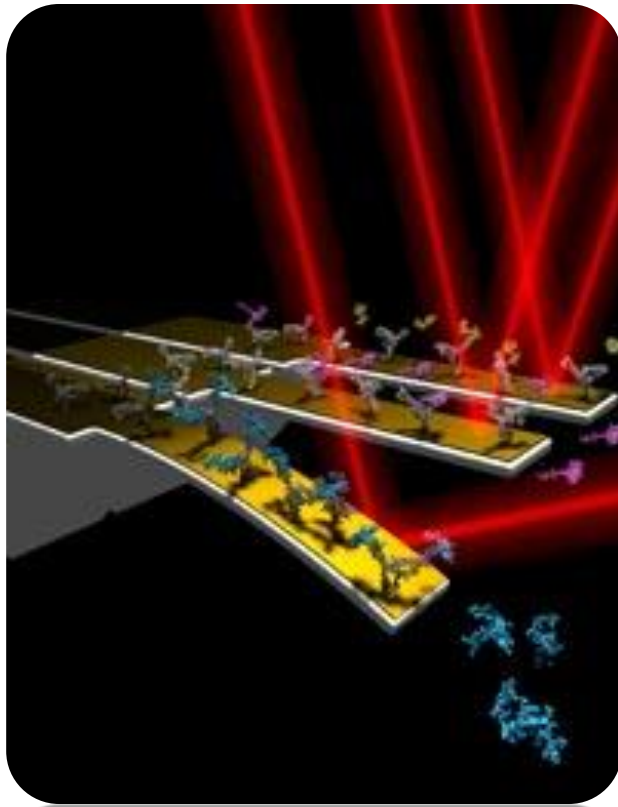


## UTILIZE HISTORICAL TECHNOLOGICAL CHARACTERISTICS

- Utilize test standards from other areas (textiles, electronics, computer assisted surgical systems, software...) as guidelines towards test methods for certain aspects of Smart System.
- Explore history of approved implants with 1 or more similar technical characteristics
- Incorporate test methods from other approved devices with similar technical characteristics
- May need to rely on different characteristics from multiple approved implants – combined can be used to “complete the story” compare for the new technology

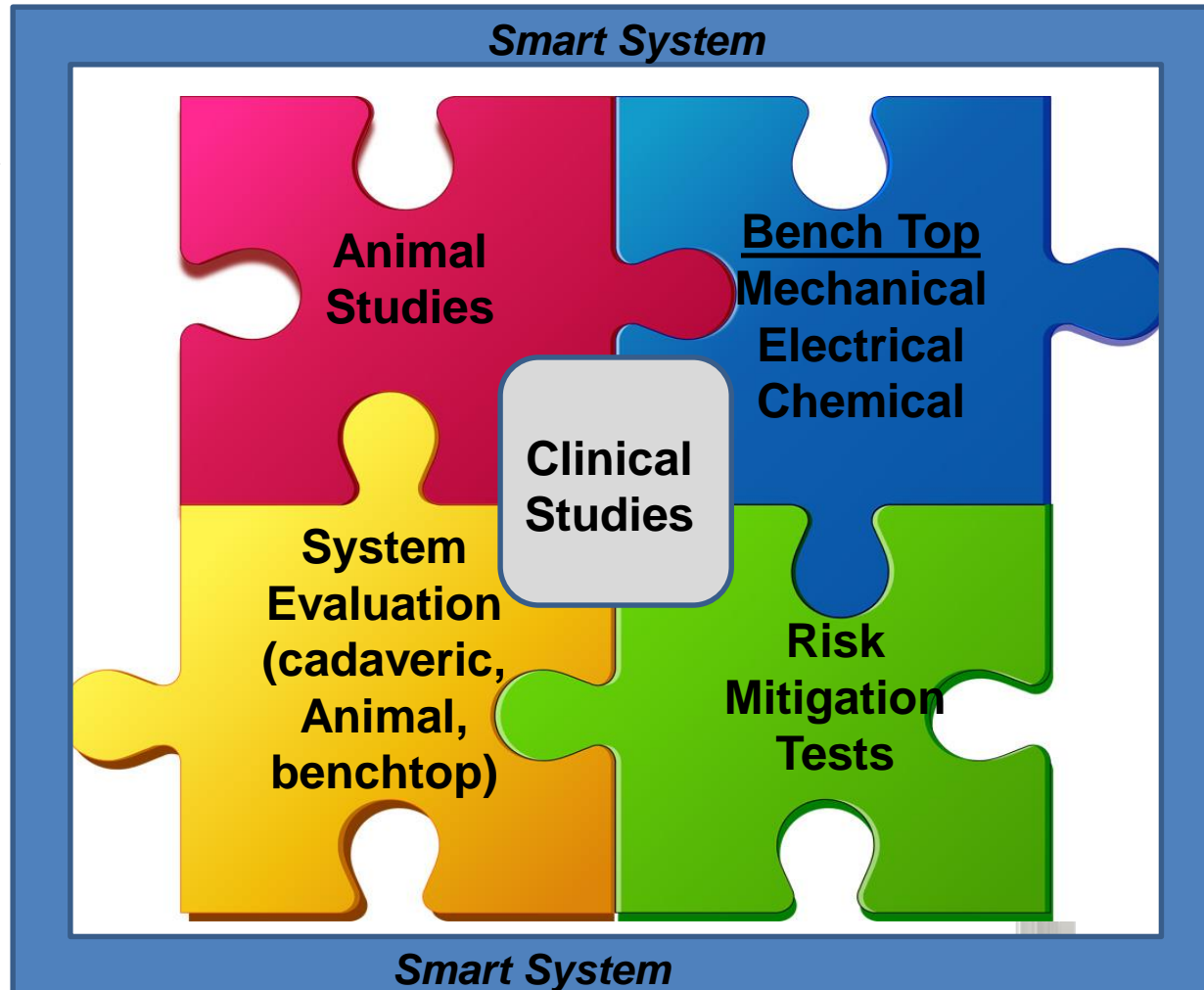


## EXAMPLE: SMART TOTAL HIP



## SAFETY EVALUATION

- Provide comprehensive tests for full safety profile
- Some tests standards may apply
- Develop applicable & new test protocols
- Address risks
- Test & validate electronics, software, housing
- Assess System as a 'whole'
- ***“Complete the story”***





# ADDRESS RISKS



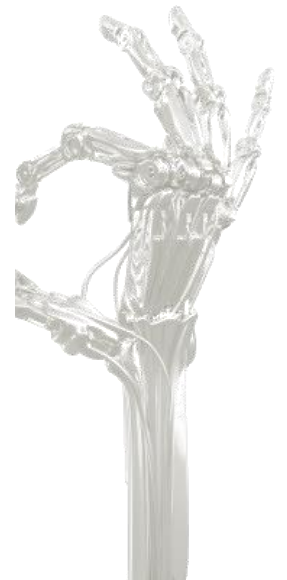
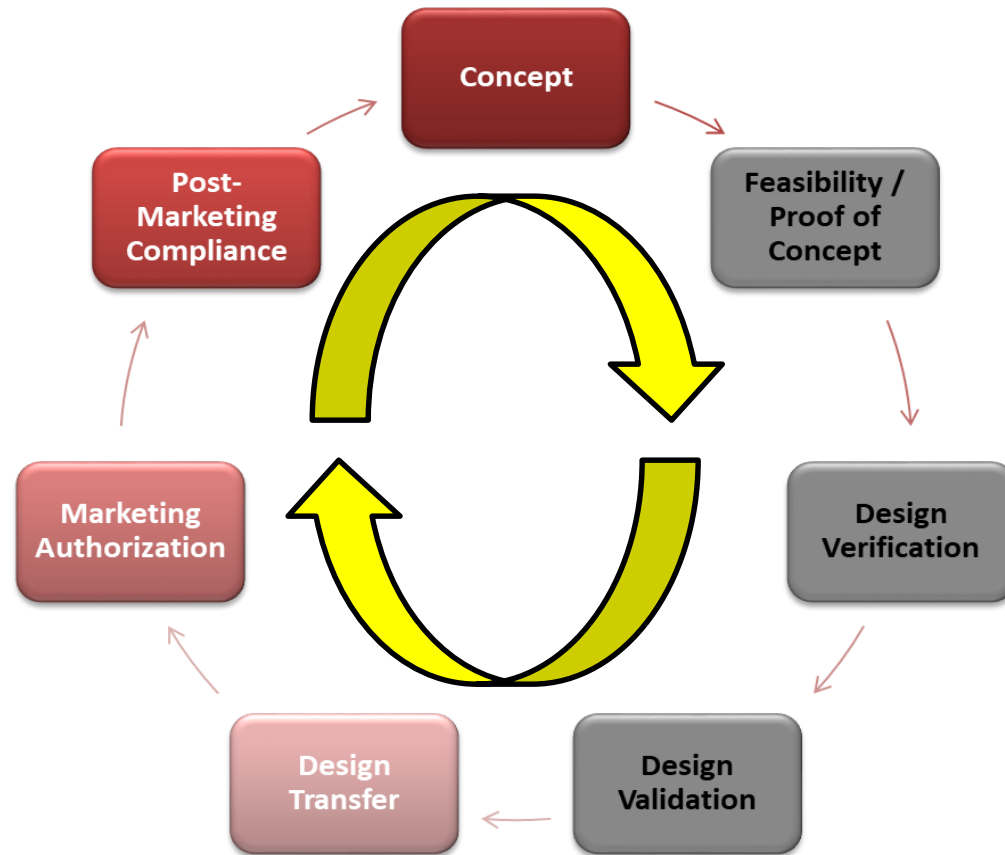
# RISK vs. CLINICAL NEED

- Balance between Safety Risk vs. Clinical Need
- Greater safety risk – Greater challenges, rigorous regulatory path & testing
- If clinical need is great - value is high – can the technology be fast-tracked?



# RISK ASSESSMENT

Continual Process throughout Product Lifecycle



# POTENTIAL RISKS OF SMART SYSTEMS

- Nanodebris, abrasion, electric charge, corrosion, residuals
- Physicochemical rxn
- Dosage & long-term effects in tissue
- Implant environment
- Interactions at bone interface, toxicity
- Strength of micro or nanostructures, flaking, delamination
- Open structures – tissue ingrowth, integration
- Effects on cell differentiation - good & bad
- New risks
- New failure modes
- New challenges
- New regulations



# KNOW THE PITFALLS

- Unrealistic goals & timelines
- Inadequate / unrealistic funding – No Shortcuts!
- Inexperienced team
- Inadequate test strategies, protocols, models
- Improper animal models = irrelevant outcomes
- Failure to conduct clinically relevant tests
- Lack of identifying, understanding failure modes
- Lack of comprehensive test plan that address many facets of smart system



# PATHWAY TO SUCCESS





## CREATE SPECIALIZED TEAM OF EXPERTS

- Team approach with seasoned experts & core competencies
- May need to form multiple teams for different smart orthopedic technologies



# EVOLUTION OF TECHNOLOGY & MEDICINE

- Continue to innovate
- Improve outcomes, quality of life, longevity
- Continue to progress – (can be good & bad)
- Our Job - minimize the “bad”



THANK YOU

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